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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/982,091 | 10/17/2001 | Akiko Kumagai | CIT1320-1 | 6755 |

7590 10/15/2004

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EXAMINER

SULLIVAN, DANIEL M

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| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,091

Applicant(s)

KUMAGAI ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
after SIX (6) MONTHS from the mailing date of this communication.
If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
earned patent term adjustment. See 37 CFR 1.704(b).

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☒ Responsive to communication(s) filed on 02 August 2004.

a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

b) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

a) ☒ Claim(s) 5, 7-15 and 23-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

b) ☐ Claim(s) _____ is/are allowed.

c) ☒ Claim(s) 5, 7-15 and 23-26 is/are rejected.

d) ☐ Claim(s) _____ is/are objected to.

e) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Specification Papers

a) ☐ The specification is objected to by the Examiner.

b) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

c) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

a) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)

Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)

Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

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DETAILED ACTION

This Non-Final Office Action is a reply to the Paper filed 2 August 2004 in reply to the Non-Final Office Action mailed 28 April 2004. Claims 1-4, 6 and 16-22 were withdrawn from consideration and claims 5 and 7-15 were considered in the 28 April Office Action. Claims 1-4, 6 and 16-22 were canceled, claims 5 and 7-9 were amended and claims 23-26 were added in the 2 August Paper. Claims 5, 7-15 and 23-26 are pending and under consideration.

Priority

For reasons of record, newly added claim 26, which is directed to a polynucleotide having a nucleotide sequence as set forth in SEQ ID NO: 3, does not find support in the prior provisional application. Therefore, the claim is afforded an effective filing date of 17 October 2001.

Response to Amendment

Claim Rejections - 35 USC § 112

Rejection of claims 8 and 11-15 under 35 U.S.C. §112, first paragraph, as lacking adequate written description for reasons of record is withdrawn.

Rejection of claims 8 and 11-15 under 35 U.S.C. §112, first paragraph, as lacking enablement for the full scope of the claimed subject matter for reasons of record is withdrawn.

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Claim Rejections - 35 USC § 102

Claims 8 and 11-15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Goodearl *et al.* (June 1999) WO 99/28470 for reasons of record and herein below in the response to arguments.

Rejection of claims 7 and 9 under 35 U.S.C. 102(e) as being anticipated by Schlegel *et al.* (International filing date: 20 February 2001) WO 01/60860 is withdrawn in view of the amendment of the claims such that they are no longer directed to a polynucleotide comprising SEQ ID NO: 3. The claims are now afforded an effective filing date of 17 October 2000.

Response to Arguments

Claim Rejections - 35 USC § 102

Claims 8 and 11-15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Goodearl *et al.*

In response to the rejection of record, Applicant alleges that the claims are distinguished from Goodearl *et al.* by consisting of a 15 continuous base segment of a polynucleotide selected from the group consisting of parts (a)-(e) of the claim. Applicant urges that the “consisting of” language of claim 8 requires that the claimed 15 base fragments cannot contain the additional nucleotides of the Goodearl *et al.* nucleic acid. This argument has been fully considered but is not deemed persuasive because claim 8 does not limit the claimed nucleic acid to “consisting of a 15 continuous base segment”. Instead, the claimed nucleic acid is limited to “having at least a 15 continuous base segment”. The only “consisting of” language present in claim 8 refers to the

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Markush group of reference sequences set forth in the claim and in no way limits the claimed nucleic acid to containing only 15 continuous bases. Instead, the claim requires only that the polynucleotide comprise at least 15 bases and is capable of specifically hybridizing under highly stringent conditions to the nucleic acids of the Markush group. As the nucleic acid of Goodearl *et al.* meets these limitations, the claim is anticipated by Goodearl *et al.*

New Grounds for Rejection

Claim construction: Upon reviewing the claims it was noted that the sequence comprised by or encoded by the claimed nucleic acids is defined in the claims using an indefinite article. For example the nucleic acid of claim 5 is limited to “having an amino acid sequence as set forth in SEQ ID NO: 2”. The broadest reasonable interpretation of this phrase is that the claimed nucleic acid can encode any amino acid sequence set forth in SEQ ID NO: 2. That is, any fragment of SEQ ID NO: 2 constitutes “an amino acid sequence” as set forth in SEQ ID NO: 2. If applicant intends that the claims should be limited to comprising or encoding the entire sequence set forth in the SEQ ID NO recited in the claims, the definite article should be used in referring to the sequence (i.e., “having the amino acid sequence as set forth in SEQ ID NO: 2”). The rejections set forth below are based on the broadest reasonable interpretation of the present claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 7-15 and 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

With regard to claim 5, the claim is directed to an isolated nucleic acid encoding a polypeptide having the functional limitation of specifically interacting with a chK1 protein and the structural limitations of an SQ/TQ motif, an isoelectric point of about 4.5 and at least one nuclear localization signal. An SQ/TQ motif is described in the paragraph bridging pages 6-7 of the specification as any serine or threonine residue adjacent to a glutamine residue. Thus the claims are generic to any nucleic acid encoding a protein that interacts specifically with chK1, has at least one serine or threonine next to a glutamine, has an isoelectric point of about 4.5 and comprises a nuclear localization signal. Although the nucleic acid is further limited to encoding a protein having “an” amino acid sequence as set forth in SEQ ID NO: 2, any two amino acid

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sequence meets this limitation (*Id.*) and therefore the limitation does not substantially limit the structure of the claimed nucleic acid.

Although, the disclosure provides two examples of polypeptides having the structural and functional limitations of the claims, i.e., human and *Xenopus* claspin polypeptides, given that the limitations of the claims encompass polypeptides of widely divergent structure, the disclosure of two homologous polypeptide sequences fails to reflect the variation within the claimed genus.

The structural limitations set forth in the claim do not adequately describe the claimed genus because they would be present in many functionally divergent polypeptides. Clearly there can be no common function ascribed to all proteins comprising a serine or threonine adjacent to a glutamine, having an isoelectric point of about 4.5 and at least one nuclear localization signal. Thus, the structural limitations are not relevant to the claimed genus because they do not define a protein having any specific function.

Likewise, the nucleic acids of claims 7-15 and 23-26 broadly encompass any nucleic acid encoding “an amino acid sequence as set forth in SEQ ID NO: 2”, “having a nucleic acid sequence set forth in SEQ ID NO: 5”, “encodes an amino acid sequence consisting of an amino acid sequence as set forth in SEQ ID NO: 4”, *etc.* The claims embrace nucleic acids having broadly divergent properties which are not adequately described in terms of structure and function.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of nucleic acids encompassed by the claims. Amending the claims to clearly

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indicate that the claimed nucleic acid must comprise or encode the entirety of the sequence identified by SEQ ID NO would overcome these grounds for rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 contains two parts (a), the first of which does not contain any limitation and the second of which is directed to a variant of the polynucleotide of (a). Parts (b) and (d) are also variants of (a), and part (d) is further directed to a variant of part (d). It is unclear what Applicant is claiming.

Claim 26 is indefinite insofar as it depends from claim 9.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 26 is rejected under 35 U.S.C. 102(e) as being anticipated by Schlegel *et al.* WO 01/60860 (previously made of record).

Claim 26 anticipated by Schlegel *et al.* for the reasons stated in the previous Office Action regarding claims 7 and 9. As stated therein, Schlegel *et al.* discloses a nucleic acid comprising a sequence that is identical to nucleotides 1-4727 of the instant SEQ ID NO:3.

In response to the previous rejection, Applicant first alleges that the nucleic acid sequence of Schlegel *et al.* contains two bases that do not match the claimed SEQ ID NO: 3 and that Schlegel *et al.* does not disclose the complete 4,756 bases of the instant SEQ ID NO: 3. With regard to the first allegation, Applicant is urged to specifically point out where the mismatched bases can be found. With regard to the second, the instant claim 26 is not limited to comprising the entire SEQ ID NO: 3. For the reasons stated in the claim construction paragraph above, the claim encompasses a nucleic acid comprising any portion of SEQ ID NO: 3. Furthermore, the claim is explicitly directed to comprising fragments of SEQ ID NO: 3, which are fully disclosed in Schlegel *et al.* Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole; therefore, the claims stand rejected under 102(e) as anticipated by Schlegel *et al.*

Although this rejection has not been set forth against claims 23 to 25 because the effective filing date of the nucleic acid sequence encoded by SEQ ID NO: 4 disclosed by Schlegel *et al.* could not be determined, it is again noted that if the nucleic acid is disclosed in any one of 60/183,319, 60/189,862, 60/207,454, 60/211,314, or 60/219,007, the 102(e) date of the Schlegel *et al.* disclosure antedates the effective filing date of the instant claims 23 to 25 and

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the claims would be anticipated by Schlegel *et al.* Although applicant argues that the claims are distinguished from Schlegel *et al.* in requiring a 4756 nucleic acid sequence that encodes a polypeptide consisting of an amino acid sequence as set forth in SEQ ID NO: 4, there is nothing in the claims that would limit the nucleic acid to 4,756 nucleotides and the polypeptide encoded by the nucleic acid of Schlegel *et al.* does, in fact, "consist of" SEQ ID NO: 4. Therefore, Applicant's assertions as to the patentable characteristics of claims 23-25 would not be found persuasive.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.
Examiner
Art Unit 1636


DAVID GUZO
PRIMARY EXAMINER